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EXAMINER

THANH, QUANG D

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/917,655

Applicant(s)

BOEKSTEGERS ET AL.

Examiner

Quang D. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 08 January 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "wherein delivering the stent includes..." lacks antecedent basis.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 29-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,290,728 in view of Lee.

3. Re claim 29-31, claims 1-2 of U.S. Patent No. 6,290,728 disclose a bypass conduit for use in a wall of a heart having all the features except for a covering that includes expandable PTFE. However, Lee teaches a graft A having an inner layer 10 and outer layer 20, both layers being made of PTFE (fig. 4, col. 4, lines 49-68 and col. 5, lines 1-3) covering the stent member 30. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device of Phelps, to include inner layer of PTFE as well as an outer layer of the same material, as suggested by Lee, for the purpose of enhance vascular patency and reducing immunogenic response (col. 4, lines 54-57).
4. Re claims 32-35, Lee also discloses the stent includes a hemocompatible and anti-thrombogenic coating of heparin on the inside surface of the stent (col. 4, line 57-64).
5. Re claim 36, claim 1 of U.S. Patent No. 6,290,728 discloses a flared end (attachment mechanism on at least one end adapted to anchor the conduit in place).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 3-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Tweden et al. (6,406,488).

8. Re claims 1 and 29, Tweden discloses a device and a method of providing blood flow directly from a left ventricle of a heart chamber to a coronary artery (see abstract), comprising:

providing a stent 10 (portions 13 and 14) (fig. 1) having sufficient strength to resist deformation from contractile cardiac forces (col. 2, lines 49-51) and flexibility in a compressed and a deployed state to permit passage to a myocardial site and remain patent when implanted (figs. 1-6, col. 3, lines 23-38); the stent includes a covering 30 on an inner surface portion and outer surface portion of the stent (fig. 2, col. 4, lines 12-18); and expanding the stent to deploy it in the passage (fig. 5-6, col. 3, lines 34-36).

9. Re claims 3-4, 9-12, 15-16, 23-26, 30-31, 36, Tweden discloses (claims 3 and 30) the covering 30 includes expanded PTFE material (col. 5, lines 2-3); (claims 4 and 31) wherein the covering covers substantially all of an inside and outside surface of the stent (col. 4, lines 50-54, fig. 2); (claims 9-10, 23-24 and 36) the stent includes a flared end 12 (fig. 1), the flared end is placed in the passage to face both the coronary vessel and the heart wall (fig.1); (claims 11-12 and 25-26) the coronary vessel is a coronary artery 82 and the heart chamber is a left ventricle 83 (fig. 1); (claims 15-16) delivering the stent includes delivering the stent percutaneously in a compressed state into a passage at the myocardial site (col. 3, lines 34-36).

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10. Re claims 5-8,17-22, and 32-35, Tweden also discloses the stent including a hemocompatible and anti-thrombogenic agent such as heparin coating over the covering on the inside surface of the stent (col. 4, lines 28-31).

11. Claims 13-14 and 27-28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tweden. Tweden discloses the myocardial site is distal to a coronary blockage 81 (fig. 1) which appears to be a partial blockage. Alternatively, if blockage 81 is not viewed to be a partial blockage then it would be obvious for a coronary blockage to be either total or partial blockage and in either case the device and method taught by Tweden still apply.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1 and 3-36 have been considered but are moot in view of the new ground(s) of rejection.

13. In response to applicant's argument re double patenting rejection of claims 29-36 that the reference Phelps (claims 1-2) fails to show the configuration providing sufficient radial strength to resist deformation from contractile cardiac forces and flexibility, the examiner disagrees. Claims 1-2 of Phelps discloses a bypass conduit for use in a wall of a heart, therefore inherently teaches that this conduit must be made of a material that has sufficient radial strength in order to resist deformation from contractile cardiac forces and thus remains patent to achieve its function of a "bypass conduit". With respect to "flexibility in compressed and deployed state", claim 2 of Phelps recites " the conduit is self-expandable", which inherently teaches the flexibility of the conduit needed to be compressed and then to expand itself in a deployed state. Regarding

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applicant's remark that Phelps does not disclose "the delivering and expanding steps", these steps are not recited in claims 29-36 of the present invention and therefore this remark is not relevant .

### ***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

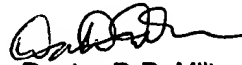
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday-Thursday & alternate Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703) 308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Quang D. Thanh  
Patent Examiner  
Art Unit 3764



**Danton D. DeMille**  
**Primary Examiner**